



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,703	10/13/2005	Motoo Sumida	47237-0528-00-US (216939)	5291
55694 7590 06/05/2009 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER LILLING, HERBERT J	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 06/05/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,703	Applicant(s) SUMIDA ET AL.	
	Examiner HERBERT J. LILLING	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-11-05;5-2-08;3-27-09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-9,11-13 and 15-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9,11-13 and 15-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-11-05;5-2-08;3-27-09</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1657

1. Receipt is acknowledged of a non-compliant response to an election requirement and an Information Disclosure Statement [IDS] filed March 27, 2009.
2. Claims 1-30 remain pending in this application.
3. Applicant has elected with traverse Invention II, Claims 10-16, and election of species which includes **Claims 10 and 14.**

Claims 1-9, 11-13 and 15-30 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 27, 2009.

The arguments pertaining to the restriction and election of species have been found not to be persuasive in view of the record. The record as submitted by the International Search Authority (ISA) stated that the claims under consideration by the ISA the following:

- a) The present patent application consists of 18 (!!) independent claims amongst a total number of claims of 30. Although claims 1, 10-21, 24, 25, 27, 28 and 30 all have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 and Rule 6 PCT.
- b) Claims 10-16 and 24 are defined as "product-by process claims", that means that a product is claimed but defined by its way of preparation. A warning is therefore given to the applicant that, when entering the national/regional phase, at least under the EPC such a claim is only regarded as novel and inventive if the product per se fulfils the requirements for novelty and inventive step.
- c) The product claims 17-20, 25 and 26 are drafted in a confusing way, so that they are obscure (Art. 6 PCT). Since it is unclear what is embraced by their scope, they are interpreted in the broadest possible way.
- d) The term "medium chain" in e.g. claim 21 is obscure since it is not clear what is embraced by "medium" (art. 6 PCT).

As stated in § 5) above, claims 1, 3-7, 9-15, 17-19 and 21-30 lack novelty and therefore an inventive step cannot be acknowledged.

Summarising, claims 1-30 lack an inventive step.

Thus, this Examiner cannot ignore the record which clearly states that there is no inventive step for the claimed subject as submitted at the time on the record. The election of a Product-by-Process as claimed and elected were clearly rejected by numerous rejections which included the latest IDS submitted for the examination by EPO on January 13, 2005 which included five references as recited in the examination:

- 1). The documents mentioned in the International search report are cited by the following abbreviations:
 - D1: PATENT ABSTRACTS OF JAPAN vol. 1999, no. 02, 26 February 1999 (1999-02-26) -& JP 10 290699 A (NIPPON SYNTHETIC CHEM IND CO LTD:THE; SHIMADA YUJI), 4 November 1998 (1998-11-04)
 - D2: TANE K ET AL: "PREPARATION OF POLYUNSATURATED OIL BY REPEATED TRANSESTERIFICATION WITH LIPASE" YUKAGAKU - JOURNAL OF THE JAPAN OIL CHEMISTS' SOCIETY, NIHON YUKAGAKU KYOKAI, TOKYO, JP, vol. 46, no. 7, 1997, pages 785-790, XP008012635 ISSN: 0513-398X
 - D3: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 04, 31 August 2000 (2000-08-31) -& JP 2000 004894 A (SUNTORY LTD; OSAKA CITY), 11 January 2000 (2000-01-11)
 - D4: PATENT ABSTRACTS OF JAPAN vol. 1996, no. 12, 26 December 1996 (1996-12-26) -& JP 08 214891 A (OSAKA CITY; MARUHA CORP), 27 August 1996 (1996-08-27)
 - D5: PATENT ABSTRACTS OF JAPAN vol. 1995, no. 01, 28 February 1995 (1995-02-28) -& JP 06 287593 A (SNOW BRAND MILK PROD CO LTD), 11 October 1994 (1994-10-11)
 - D7: JIM-WEN LIU, EMIL G BOBIK JR AND YUNG-SHENG HUANG: "In Vitro hydrolysis of Fungal oils:Distribution of Arachidonic acid-containing triacylglycerol molecular species" JAOCS, vol. 75, no. 4, 1998, pages 507-510, XP009027963

The support by the ISA that the claimed subject matter had been considered the claimed inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Art Unit: 1657

The restriction and election of species have been made **Final**.

4. In accordance with this Tech Center Policy based on above restriction containing product claims and process claims, this Examiner will rejoin any non-elected process claims upon the election of a product claim which is subsequently is found allowable in view of the following guidelines:

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. **Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.** Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1657

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipatory by:

1. PATENT ABSTRACTS OF JAPAN vol. 1999, no. 02, 26 Feb 1999 (1999-02-26) -& JP 10 290699 A (NIPPON SYNTHETIC CHEM IND CO LTD;THE; SHIMADA YUJI), 4 November 1998 (1998-11-04) ;

2. TANE K ET AL: "PREPARATION OF POLYUNSATURATED OIL BY REPEATED TRANSESTERIFICATION." YUKAGAKU - JOURNAL OF THE JAPAN OIL CHEMISTS' SOCIETY, NIHON YUKAGAKU KYOKAI, TOKYO, JP, vol. 46, no. 7, 1997, pages 785-790, .XPOO801263B

3. PATENT ABSTRACTS OF JAPAN vol. 2000, no. 04, 31 August 2000 (2000-08-31) -& JP 2000 004894 A (SUNTORY LTD; OSAKA CITY),-11 January 2000 (2000-01-11);

4. Jim-Wen Liu et al, in vitro hydrolysis of fungal oils: distribution of arachidonic acid-containing triacylglycerol molecular species, JAOCS, vol. 75, no. 4, p507-510, 1998. Abstract, page 507-509

5. Akimoto et al., EP 0 965 578 A1 Publication: 22.12.1999.

Each of the above following references anticipates the claimed product which recites the following:

"10. A transesterified oil/fat or triglyceride obtained by a production process according to claim 1 [which claim 1 recites the following: A production process for a transesterified oil/fat or triglyceride, by transesterification of 50-100 parts by weight of one or more fungus-produced oils/fats or triglycerides containing at least 20% of polyunsaturated fatty acids containing 20 or more carbons and two or more double bonds and 0-50 parts by weight of one or more vegetable oils/fats or triglycerides, using a 1,3-position specific type lipase] ."

Art Unit: 1657

And for dependent claim, which species has been elected recites:

“14. A transesterified oil/fat or triglyceride containing at least 20% of arachidonic acid, obtained by a production process according to claim 1, [which claim 1 recites the following: A production process for a transesterified oil/fat or triglyceride, by transesterification of 50-100 parts by weight of one or more fungus-produced oils/fats or triglycerides containing at least 20% of polyunsaturated fatty acids containing 20 or more carbons and two or more double bonds and 0-50 parts by weight of one or more vegetable oils/fats or triglycerides, using a 1,3-position specific type lipase] and which contains at least 40% of triglycerides with one residue of arachidonic acid in the molecule and/or no more than 4.0% of AAA, wherein AAA is a triglyceride with 3 residues of arachidonic acid in the molecule.”

The claim(s) are drawn to a product which each reference teaches a structure of an arachidonic acid glyceride. It is immaterial how the structure is prepared as long as the product per se is the same absent a showing to the contrary; see **In re Brown**, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977):

“It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products,”

Art Unit: 1657

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto et al., EP 0 965 578 A1 Publication: 22.12.1999

alone or further in view of:

1. PATENT ABSTRACTS OF JAPAN vol. 1999, no. 02, 26 Feb 1999 (1999-02-26) -& JP 10 290699 A (NIPPON SYNTHETIC CHEM IND CO LTD: THE; SHIMADA YUJI), 4 November 1998 (1998-11-04);

2. TANE K ET AL: "PREPARATION OF POLYUNSATURATED OIL BY REPEATED TRANSESTERIFICATION." YUKAGAKU - JOURNAL OF THE JAPAN OIL CHEMISTS' SOCIETY, NIHON YUKAGAKU KYOKAI, TOKYO, JP, vol. 46, no. 7, 1997, pages 785-790, .XPOO801263B

3. PATENT ABSTRACTS OF JAPAN vol. 2000, no. 04, 31 August 2000 (2000-08-31) -& JP 2000 004894 A (SUNTORY LTD; OSAKA CITY),-11 January 2000 (2000-01-11);

4. Jim-Wen Liu et al, in vitro hydrolysis of fungal oils: distribution of arachidonic acid-containing triacylglycerol molecular species, JAOCS, vol. 75, no. 4, p507-510, 1998. Abstract, page 507-509.

Akimoto et al teaches the transesterification with 1,3 lipases to produce unsaturated triglycerides which includes arachidonic acid at the various positions which arachidonic acid contains 20 or more carbons and two or more double bonds as disclosed in Table 1 and examples which includes Examples 4, 5, 6 Table 2. If there are any differences with respect to the claimed product per se, these differences would have been prima facie obvious absent a showing to the contrary for the claimed process steps which lack any unexpected process step(s) or product - by- process conditions, which differences in view of the disclosure of Akimoto et al alone or further in view of the above additional references to prepare the claimed product in view of the Supreme Court's decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it. However, the Guidelines explain that there is no requirement that patent

Art Unit: 1657

examiners use the TSM approach in order to make a proper obviousness rejection. Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention that invention may still be found obvious.

If there are any differences with respect to the claimed subject matter and the general knowledge pertaining to the art in the area, that these differences would have been prima facie obvious to one of ordinary skilled in the pertinent art whether it was based on the art of record or claimed subject would have obvious for the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results”.

The KSR Decision requires rationales to support the rejections under 35 USC 103. The first issue is to analyze the Graham factual inquires as noted above for obviousness based of the prior art but the prior art is not limited to references but includes the basic knowledge and understanding of one skill in the pertinent art. Thus, the prior art alone or in combination does not have to teach or suggest or motivate one all of the limitations of the claimed limitations but there must be some rationale to explain these differences would have been obvious to one of ordinary skill in the art.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. **No claim is allowed.**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HERBERT J. LILLING whose telephone number is 571-272-0918. The examiner can normally be reached on WORK AT HOME MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JON WEBER can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918

Art Unit **1657**

June 04, 2009

/HERBERT J LILLING/
Primary Examiner, Art Unit 1657